

CATARACT DATA COLLECTION PROTOCOL

OUTCOMES MEASUREMENT CONSORTIA (OMC)

The American Medical Group Association serves the needs of group practices committed to providing the highest quality cost-effective health care to their patients. AMGA is dedicated to the continuous improvement of the group practice of medicine. In order to promote and improve medical care by group practices, AMGA and over 60 of its members have agreed to participate in a project that will expand the use of patient outcomes measurement in routine medical care. The focus of the effort will be patients diagnosed as having diabetes, asthma, hypertension, and low back pain, and patients undergoing total hip replacement, total knee replacement, or cataract surgery.

Objectives of the OMC include:

- Assessment of the health status of particular groups of patients and track changes in their clinical and functional status over time.
- Assessment of the effectiveness of treatment alternatives based on the effect on patients' overall health.
- Enhancement of continuous quality improvement efforts by using outcomes information to target areas needing improvement.
- Evaluation of patient outcomes across systems of care.
- Provision of better feedback to physicians and staff.

QUESTIONS OF INTEREST REGARDING CATARACT SURGERY

- What changes in visual acuity occurred as a result of cataract extraction?
- From the patient's point of view, has there been improvement in sight?
- Has the visual functional status of the patient improved as a result of the surgery?

THE SAMPLE

All consecutive patients having extracapsular cataract extractions with implants (planned ECCE or phaco emulsification) will constitute the sample. Secondary implants or cataract surgery combined with other procedures such as trabeculectomy will not be included. As a data validity measure, each participating clinic must provide the total number of consecutive patients enrolled in the project and the total number of cataract surgeries performed during the sampling period. A monthly patient log should be kept that records both the total number of patients eligible to be included in the study sample and those that actually become part of the study sample (enrolled vs. eligible patients). Enrolled patients will also be kept track of through recording loss-due-to-follow-up.

SECOND EYE PROTOCOL

Many patients have cataracts in both eyes. Most clinics routinely handle such patients by performing cataract surgeries sequentially. After the surgical removal of one cataract, the eye is allowed to heal, and then surgery is scheduled for the other eye (so that the patient can see well enough to function during the healing process). In order to collect the most meaningful data, the following protocol should be followed when dealing with a cataract surgery on the second eye.

1. If surgery is done on the second eye **after** the first eye study is complete (i.e. **more than 9 months post-op**), then the study should be restarted for the second eye as if it were a new patient. (The patient should have already filled out their six month follow-up forms, so the study on the outcomes of the first surgery is complete.) In these cases, all pre-operative forms should be filled out by both the patients and physicians.

2. If surgery is done on the second eye **before** the first eye study is complete (i.e. **before the six-month follow-up visit**), the following protocol is to be followed:
 - At the pre-op visit for the second eye, the patient will fill out the patient post-op cataract questionnaire (Form 3.5), which completes the patient questionnaire aspect of the first eye study.
 - Data from the patient post-op cataract questionnaire (Form 3.5) for the first eye will serve as baseline data for the patient pre-op cataract questionnaire (Form 3.1) for the second eye.
 - At the time to the patient pre-op visit for the second eye, the physician will fill out the physician post-op evaluation (Form 3.4) for the first eye, thus completing the study for the first eye. The physician pre-op evaluation (Form 3.2) will then be filled out for the second eye.
 - At the time of the patient follow-up visit for the second eye, the **operated eye** portion (first page) and **visual acuity level (for non-operated eye only!)** (second page) of the physician post-op evaluation (Form 3.4) should be filled out.

All other forms should be used at the appropriate time per the regular protocol (i.e. the physician should fill out the Intraoperative Evaluation Form 3.3 on the day of surgery, etc.)

INSTRUMENTS

All data collection instruments must be labeled with identification numbers for patient, physician, and clinic. If the clinic has labels available, these will be affixed to the instruments; otherwise the identification box must be manually completed (with patient ID, Physician ID, and Clinic ID codes).

All project sites enrolling cataract patients will use the following data collection instruments:

1. *Personal Identifiers Form*: While all clinics must collect this data, the use of this particular form is optional. It may be used as a cover sheet to keep the forms organized.
2. *Face Sheet*: This form is for internal use only, and will not be submitted to AMGA or a data pool. Intended to be used as part of a tickler file system, it may be customized for each clinic, as long as it provides a system for assessing the quality of data capture.
3. *Patient Log*: This form will document information about all patients eligible for the study and dates of enrollment (or reasons for non-enrollment if not enrolled). The log will be an essential part of the tickler system, as well as allow clinics to determine an accurate denominator (enrolled versus eligible patients).
4. *Personal Characteristics Form*: The demographic and comorbidity data on this form must be collected for basic data analysis. This form will be completed by the patient at the time of enrollment.
5. *Patient Questionnaires, Cataract Forms 3.1 and 3.5*: These forms ask the patient about his/her vision, and must be completed pre- and postoperatively.
6. *Physician Questionnaires*:
 - Preoperative Evaluation Form 3.2, to be completed at the last pre-op visit.
 - Intraoperative Report Form 3.3, to be completed on the day of surgery.
 - Postoperative Evaluation Form 3.4, to be completed approx. 6 months post-op.

Clarification: Preoperative Evaluation Form 3.2

–Past Medical History—Medications list—“none” means “none of the above”

–NSAIDS to be included with ASA

–if diagnosis of ocular hypertension with **no other** abnormalities, list patient as normal

–Past Ocular History—Glaucoma—“field loss” means from any etiology

Clarification: Postoperative Evaluation Form 3.4

–Interventions—“Eyeglass Rx” means “Eyeglass Rx received by and filled by patient

–NOTES/COMMENTS area—record any clinically significant events that are related to categories of objective findings during the postoperative evaluation

7. *Process Information Form*: This form will be completed by the patient at the time of enrollment. Since the form will be used to evaluate the data collection process, this form must be filled out last (after all other forms given to the patient).
8. *Loss to Follow-Up Log*: This form will document information about all patients who are eligible and participating in the study, but have been lost due to follow-up (no longer participating in the study due to death, refusal to participate, relocation, etc.). Reasons for non-participation will be documented.

DATA COLLECTION PROCEDURES

1. Time Frame

- a. Initiation of the project
Staff:
 Print labels for all forms.
 Develop a schedule and assign responsibilities for form submission.
- b. Pre-operative visit
Patient:
 Personal Identifiers Form
 Personal Characteristics Form
 Patient Questionnaire Cataract Form 3.1
 Process Information Form (must be last form completed)
Physician:
 Pre-operative Evaluation Form 3.2
- c. Intraoperative
Physician:
 Intraoperative Form 3.3
- d. **OPTIONAL**
Post-operative (approximately six weeks post-op, with a data collection window of 2–8 weeks)
Patient:
 Patient Questionnaire Cataract Form 3.5
Physician:
 Post-operative Early Evaluation Form 3.4
- e. **STANDARD**
Post-operative (targeted for 6 months post-op, with a data collection window of 2–9 months)
Patient:
 Patient Questionnaire Cataract Form 3.5
Physician:
 Post-operative Standard Evaluation Form 3.4

2. Patient Questionnaires

At the patient's last **preoperative** visit before surgery, the staff will:

- a. Affix an identification label to the first page of the patient identifiers form, the personal characteristics form, the Health Status Questionnaire, the Patient Questionnaire (Form 3.1) and the process information form. If the questionnaire is administered by mail, it should be accompanied by a letter, which may be tailored by each site.
- b. Record today's date, and complete any other information requested on the front of the form.
- c. Give questionnaire to the patient and explain that his/her responses to the questions will help improve the clinic's care for all patients.

Suggested Script: _____ is committed to **measuring quality of care**. Since you are scheduled for cataract surgery, please complete these questions about your vision and your overall health. It will take you about **20–30** minutes. You will also be asked to complete a short questionnaire approximately six months after your surgery.

Your doctor asks for this information as a routine part of your care. We consider this information as important to you and to your doctor as a lab test or x-ray. **Your answers are important and will help your physician understand how you are doing, so please fill out the questionnaires completely and return it to _____.**

The description of the purpose of these questionnaires is very important. It should be described consistently by all persons distributing the questionnaires to patients. Project sites may wish to incorporate a cover letter into their patient questionnaires that provides the description and purpose of the study and also provides instructions for the patient to accurately and correctly complete the patient questionnaire. If the patient should require assistance, the questions should be **read rather than interpreted**. If you believe that more assistance was given than just reading the questionnaire, please note that fact in the “Administrative Use Only” box on the front of the questionnaire.

If necessary, the forms may be mailed to the patient 4-6 weeks prior to surgery along with a cover letter and return envelope.

d. Review forms for completeness, and discuss any questions left unanswered with the patient.

If the patient refuses to complete the questionnaires, record the reason on the front of the questionnaire in the box marked “ADMINISTRATIVE USE ONLY.” Please code refusals as follows:

Time: Patient does not have the time

Read: Patient could not read form

Conf: Perceived violation of confidentiality

Unab: Unable to complete

Other: Any other stated reason

e. Make sure that the patient completes the **entire** form by the end of the physician visit. If the patient cannot stay long enough to complete the form, ask that he/she take the form home to complete and mail it back as soon as possible. Give him/her a self-addressed, postage paid envelope. Note on the patient’s tickler file that he/she received the form, and schedule a date to follow-up regarding the form’s completion.

f. Return all completed forms to the Project Coordinator.

3. **Physician Preoperative Evaluation**

At the last visit before surgery (but no more than four to six weeks prior to the procedure), the staff will:

a. Affix an identification label to the front of the Physician Preoperative Evaluation form.

b. Record the dates of the pre-op visit and the scheduled surgery.

c. Give the form to the physician to begin completing the physician’s portion. (Some physician/assistant teams may differ in who completes clinical measurements. The key is that the **forms are completed**).

d. Verify that the Physician Preoperative section is complete prior to surgery.

e. Return the completed forms to the Project Coordinator.

The goal is to complete these forms as part of routine care and have them completed for 100% of cataract patients.

4. **Physician Intraoperative Report**

The physician should complete an Intraoperative Report on the day of surgery. The staff will:

a. Affix an identification label to the front of the Intraoperative Report.

b. Record the surgery date.

c. Give the form to the physician for completion.

- d. Place a card for each patient in a tickler file (computerized or manual), noting the date of surgery and the date at which six-month follow-up should occur.
- e. Return completed form to Project Coordinator.

5. Physician Postoperative Evaluation Form

NOTE: Prior to postoperative evaluation, YAG laser capsulotomy may be performed on the patient; example—if decrease in VA because of opacity of posterior capsule, perform YAG and then do postoperative evaluation in 2–3 weeks

Six months following surgery, the patient will return for a formal office visit that will be recorded by the physician/staff on the postoperative data form. The staff will:

- a. Affix an identification label to the front of the Physician Postoperative Evaluation form.
- b. Record the dates of surgery and the post-op visit.
- c. Give the form to the physician for completion.
- d. Check forms for completeness.
- e. Note on the patient's tickler file (computerized or manual) the date of surgery and the date at which Patient Postoperative Questionnaire follow-up should occur.
- f. Return completed form to Project Coordinator.

6. Patient Postoperative Questionnaire

The Patient Postoperative Questionnaire Form 3.1 will be distributed within four weeks of the patient's six-month postoperative physician visit. It can be administered at the six-month follow-up visit if no treatment interventions (eg yag, new eyeglass Rx) are planned.

If no six-month follow-up patient form has been completed two weeks after the follow-up date, staff will notify the patient and try to elicit the responses to the questionnaire over the phone. Staff will note on the front of the questionnaire that answers were obtained by phone. If patient refuses to respond, no further attempts will be made to obtain postoperative information until the patient's one year postoperative visit.

7. Forms Editing

Patient forms should be reviewed for completeness by staff while the patient is still in the office. The project coordinator will again review the forms for completeness and will attempt to contact the patient/physician for missing responses.

8. Sample Log

All patients sampled for the project should be included in a log that records the following information:

- Unique identification number
- Patient's last name
- Date of Surgery
- M.D. (doctor's initials)
 - Operative eye: OD/OS
 - Patient Enrolled? (Yes/No)
- Reason for non-enrollment (comment)